



## Department of Energy

Washington, DC 20585

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**MEMORANDUM FOR:** Field Patent Counsels

**FROM:**

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for Technology Transfer  
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**SUBJECT:** Bailment of Biological Materials and Tangible Research Products

Under the technology transfer authorities of 48 CFR Part 970.52 and DOE's M&O contracts, Laboratory Biological Materials and Laboratory Tangible Research Products (LBM/LTRP) may be bailed to outside entities (Bailees) by DOE's M&O Contractors (Bailors) having technology transfer as a mission.<sup>1</sup> Bailments are considered a technology transfer mechanism similar to the licensing of Contractor owned Subject Inventions and copyrights. Since the Government retains ownership of the LBM/LTRP provided under Bailments, DOE has the right to provide instructions and terms and conditions under which the Contractors can bail such materials/products in addition to those provided in the Contractor's M&O contracts.

**A. General considerations:**

- 1) Where possible and appropriate, patent protection will be sought for these materials/products, but the absence of such protection does not preclude Bailments.
- 2) Bailments must not adversely affect ongoing DOE research.
- 3) A decision by the Contractors to bail, but not file patent applications, does not preclude DOE from seeking patent protection. However, DOE may choose not to file patent applications as described in paragraph B.1 below.
- 4) Bailments may create statutory bars. Contractors shall provide adequate notice and time for DOE to file patent applications, consistent with M&O Contract requirements, prior to Bailments occurring.

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<sup>1</sup> For the purposes of this IPI, the definitions of "Laboratory Biological Materials," "Laboratory Tangible Research Products," and "Bailment" are set forth in 48 CFR Part 970. Although naturally occurring biological materials do not fall under the definition of Laboratory Biological Materials, this IPI is to be applied to Bailments of such materials, except for the treatment of fees received as discussed in C.3.



- 5) Ownership of the bailed LBM/LTRP and unmodified progeny/unaltered derivatives remains in the Government.
- 6) Normally, Bailment agreements shall include indemnity provisions for product liability, patent infringement and general liability to cover the use of the materials/products and any progeny and derivatives thereof. As appropriate for the specific situation, there may need to be flowdown of indemnity provisions if the Bailee will be further bailing the LBM/LTRP.
- 7) When the Bailment is not incidental to another technology transfer mechanism, the Contractor and Government do not, as a condition of the Bailment, receive rights in any intellectual property that may result from the Bailee's use of the LBM/LTRP and any progeny or derivatives. In the case where the Bailment is used in conjunction with another technology transfer mechanism, (e.g., WFO, CRADAs, patent licensing, consulting services) the terms of that specific technology transfer agreement shall govern the disposition of IP rights.
- 8) The Bailment agreement shall not reflect that the Bailee is required to conduct research using the LBM/LTRP, but the agreement may prohibit the Bailee from engaging in commercialization.
- 9) Bailment agreements shall include the technology transfer provisions, such as U.S. Competitiveness, required by the M&O contracts. Administrative technology transfer requirements, including Fairness of Opportunity and Conflict of Interest, shall be adhered to. To ensure fairness of opportunity, there must be equal opportunity and access to the LBM/LTRP (although greater consideration to U.S. based Bailees may be given).
- 10) The choice of technology transfer mechanism (e.g., Bailment, WFO, CRADAs, patent licensing, consulting services) should be appropriate for the transaction. Bailment provisions may be included in other agreements (WFO, CRADA, etc.) where Bailments are collateral to a broader research effort.
- 11) The Technology Transfer authority to do bailments shall not be used to make DOE's research laboratories into what amounts to production facilities, producing large quantities of LBM/LTRP for Bailments. DOE HQ Program Office(s) shall provide guidance consistent with the Program's mission as to number of Bailments and amount of material that can be bailed directly to customers under the Technology Transfer authority. Where the actual or anticipated demand exceeds the guidance threshold, the Contractor shall bail the LBM/LTRP to available commercial suppliers, who shall then supply industry. In the event the laboratories begin producing substantial quantities of LBM/LTRP, we have been informed by

DOE's environmental legal office that a study of the laboratories' Bailment program may be necessary to determine if further environmental review is necessary.

- 12) The Contractor shall include agreement language requiring the Bailee to comply with all applicable federal, state and local laws and regulations, including environment, safety and health, export control, and those covering human subject and animal use. Bailee shall agree to comply with 21 CFR Part 50, 45 CFR Part 46 and 10 CFR Part 745 for research involving human subjects or clinical trials. Bailee shall further agree not to use the LBM/LTRP for research involving human subjects or clinical trials outside of the United States without notifying the Contractor and DOE, in writing, of such research or trials and shall agree to comply with the applicable regulations of the appropriate national control authorities. Written notice to the Contractor and DOE of research involving human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of such research or trials.
- 13) There must be a written formal contractual agreement between the Contractor and the Bailee before Bailment of any LBM/LTRPs. Collegial exchanges and other similar interactions are not considered technology transfer agreements and are not covered by this IPI.

#### **B. Specific considerations**

- 1) Where patent protection will not be sought by the Contractor, DOE may determine that it does not wish to seek patent protection and may authorize the Contractor to distribute the unpatented LBM/LTRP through the Bailment process, where the Contractor agrees to the following:
  - a) The Contractor shall make a written request to the cognizant DOE Operations Office, Patent Counsel;
  - b) Information describing the invention (LBM/LTRP) shall be made publicly available either through publication in the scientific literature or by other appropriate means;
  - c) Negotiated Bailment terms and conditions shall ensure that the LBM/LTRP will remain available to the non-profit research community. Generally, this can be accomplished through non-exclusive Bailments, or exclusive Bailments for distribution or sale of the materials/products. Any exclusive Bailment must provide for conversion to non-exclusive status or termination of Bailee's rights upon failure to comply with the terms addressing continuing availability;

- d) If an exclusive Bailment is executed, provision must be made for independent maintenance of the material, such as at a national repository, or the originating Contractor laboratory;
  - e) The Government retains ownership of the LBM/LTRP and shall have a world-wide, irrevocable, unlimited royalty-free, paid-up license in any intellectual property, e.g., patent applications and patents, covering the LBM/LTRP to make, use or distribute, or to have made, used or distributed the LBM/LTRP for the Government. Upon request, sufficient quantities of the LBM/LTRP shall be provided to the Government by the Contractor along with necessary documentation to preserve, use, and replicate the material to meet Government needs; and
  - f) If, after reasonable notice to the Contractor, the Contractor fails to fulfill the conditions of paragraphs a-d above, DOE shall automatically have the right to: (i) distribute the LBM/LTRP, or (ii) revoke the Contractor's authority to distribute the material.
- 2) The Contractor shall seek patent protection for the LBM/LTRP being bailed in those situations where an exclusive Bailee will be using the LBM/LTRP for purposes other than the Bailee being a distributor.

### **C. Special Considerations**

- 1) If LBM/LTRP that is contemplated for Bailment to a commercial entity was, may have been, or may yet be created under a government purpose license to a third-party's intellectual property, then that commercial entity must indemnify the Contractor and DOE for patent infringement and/or demonstrate that it has and will continue to have a valid license to practice the applicable patent(s) during the term of the Bailment. Indemnity and/or valid license are required because Bailment of such LBM/LTRP made under a government purpose license(s) in a government research program may fall outside of the protection/scope of that license(s) where the LBM/LTRP is bailed to a commercial entity,
- 2) When the bailed material is an animal, there is a potential for a Bailee's animal colony to become infected by bailed biological material. The Bailment agreement must include appropriate disclaimer and hold harmless provisions to protect the Contractor and DOE.
- 3) Bailment fees (excluding reimbursement costs) received from the Bailee for non-naturally occurring LBM/LTRP are considered royalties and may be retained by the Contractor for use in accordance with 48 CFR Part 970.52 and its M&O contract. In the event any laboratory contemplates Bailing naturally occurring LBM/LTRP,

this office should be notified and we will obtain a legal opinion as to how those Bailment fees are to be treated. Nothing in this Bailment IPI is to be construed as authority or any indication that there is any authority to license technical data. Licensing of technical data alone, which is not otherwise protected, is contrary to DOE policy.